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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/29/2001

Chen Xing Su

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21999

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07/18/2008

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EXAMINER

LEITH, PATRICIA A

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/997,588	Applicant(s) SU ET AL.	
	Examiner Patricia Leith	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-28 is/are pending in the application.
- 4a) Of the above claim(s) 13-23,27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-12 and 24-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/4/2008 has been entered.

Claims 1 and 5-28 are pending in the application.

Claims 13-23 and 27-28 were withdrawn on the merits as they are directed toward a non-elected invention.

Claims 1, 5-12 and 24-26 were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-8 are is dependant upon claim 4 which is canceled. Therefore, the metes and bounds of claims 5-8 cannot be readily determined. It is thought that Applicants mean for claims 5 – 8 to be dependant upon claim 1 and therefore, claims 5-8 were examined on the merits as if claims 5-8 were dependant upon claim 1.

Correction is necessary.

Claim Rejections - 35 USC § 103

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) and further in view of Gagnon (1997) in view of Elliot (US 1,885,401) and further in view of Beaven (GB 2215173A) and Astrauskas et al. (US 3,953,582).

Claims 1, 5-12 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) in view of Gagnon (1997) in view of Brock et al. (1991) in view of Nahir (EP 0 555 573 A1) in view of Elliot (US 1,885,401) and further in view of Beaven (GB 2215173A) and Astrauskas et al. (US 3,953,582).

The teachings of Schechter, Gagnon, Elliot, Brock et al. and Nahir were keenly discussed in previous Office actions. None of the references specifically taught holding MC fruit in a plastic-lined containers or wherein the centrifuge pressure was operated between 1 and 1000 psig.

The use of plastic containers to store or place fruit in were well-known at the time the invention was made. Beaven (GB 2215173A) for example, disclosed a transparent, ventilated portable plastic container for carrying and ripening of fruits or vegetables (see entire reference, especially Abstract and figure 2).

Astrauskas et al. (US 3,953,582) disclosed that centrifuges using 150 psi pressure were known in the art for separation of solids from liquids:

The utility and hence the commercial applicability of the continuous process of Kawakami et al. is limited by the difficulty involved in the recovery of the basic alkali metal azide (the double salt) from the liquid ammonia carrier. Typically, solids suspended in liquids can be recovered by continuous centrifuging. However, centrifuges capable of operation at pressures in excess of about 150 psi are unknown. Pressure leaf filters can be employed but equipment costs and operating costs are high and such a system is not

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continuous. Kawakami et al. note that filtration methods are far from satisfactory. Evaporation of the ammonia to recover the double salt can likewise involve the erection of costly equipment and operation is expensive. (col. 1, lines 40-54)

One of ordinary skill in the art would have been motivated to place or store MC fruit in plastic containers such as the ones disclosed by Beaven in order to either ripen the MC fruits or to transport the MC fruit to the fruit processing plant/facility. The ordinary artisan would have had a reasonable expectation of success in producing the claimed invention, in that the use of plastic containers were known for fruit/vegetable storage and for ripening.

It was clear that centrifuges which operated at about 150 psi were known in the art at the time the invention was made according to Astrauskas et al. Although Astrauskas et al. is not directed toward the separation of fruit juices, it is deemed that the ordinary artisan would draw upon the teachings in the prior art regarding centrifuges which were capable of separating the liquid and juice of solids as per the teachings of Elliot and would have had a reasonable expectation that a centrifuge operating at 150 psi would have successfully carried out separation of the liquid from the solid material. It is noted that $\text{psi} = \text{psig} + 14.695948804$ (atmospheric pressure). And therefore, the teachings of Astauskas et al. teaching $150 \text{ psi} - 14.7$ (approx) = 135.3 psig is within the psig as Instantly claimed.

Response to Arguments

Applicant broadly argues that the cited references do not teach every aspect of the claimed invention (p. 8, Remarks)). Applicant specifically argues that “The method of making the product and the various constitutive elements added to the product before delivery have a significant effect on lipidperoxidation inhibition... (p. 8, Remarks). However, to reiterate from the previous Office Action, this appears to be unsubstantiated allegation, as Applicant has not provided any convincing arguments nor evidence that would demonstrate that MCJ made by the claimed method would provide for ‘increased capacity’ of inhibiting lipidperoxidation. It remains deemed that the fruit juice as processed according to the claims is the same juice disclosed in the prior art, or so similar that no discernable differences could be made.

Applicant argues that an article submitted by Applicants, namely “Drug Development; The Pain Killer Tree: An Ancient Remedy Rediscovered” teaches that unexpected results are achieved when different processing steps are utilized (p. 8, Remarks). However, there is nowhere in the disclosure of this reference which indicates that the process *steps of the claimed invention* provides for any unexpected results. While not specifically argued in this amendment submitted by Applicants it is again reiterated that the data found in 60/251,417 does not substantiate the allegation

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that TNJ 'out performed' other MC juices/products, only that it has better oxygen scavenging capabilities than that of Vitamin C and grape extract.

Applicant argues that "Chye provides a non-enabling disclosure, which indicates that 'noni-juice is the new darling of health-conscious malaysians'....(p. 9, Remarks) However, Chye is enabling for the use of MC juice as being used (consumed) by the public for health concerns. It is clear from Chye that MC juice was widely consumed.

Applicants argues that Schechter "does not describe a method of processing and administering the noni fruit so as to provide a stronger scavenging effect.." (p. 14, Remarks). However, Applicants are arguing one reference, wherein the rejection as a whole is made over several references rendering the claims *prima facie* obvious.

Applicants argue that Elliot does not teach 1) allowing the fruit to ripen for 0 to 14 days, preparing said harvested fruit for extraction, placing the ripened fruit in plastic lined containers, holding the fruit in said containers for 0 to 30 days, filtering with a screen filter size between 1 and 2000 microns, or wherein the filter pressure is between 0.1 psig to 1000 psig (p. 9, Remarks).

However, it is first noted that the limitations of allowing the fruit to ripen for 0 to 14 days as well as holding the fruit in said containers for 0 to 30 days are essentially non-limitations because these steps do not need to occur (i.e., a step occurring for 0

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days does not need to occur). Secondly, the phrase 'preparing said harvested fruit for extraction' is quite broad and does not include any specific method steps. This phrase can be merely directed toward mechanically separating the rind and seeds for example, from the fruit which is clearly taught by Elliot. Additionally, contrary to Applicants' assertion, it was pointed out in the non-final Office action of 1/24/2007 that Elliot specifically disclosed the use of an 80 mesh filter and it was also relayed that 80 mesh = 177 microns, thereby making obvious this limitation found in the claims. While Elliot does not specifically teach placing fruit in a plastic container, it would be well-understood in the art that the fruit picked from the tree would need to be held in some type of container in order to at least transport the fruit from the orchard or harvesting place to the place where the juice is prepared. The phrase which states holding the fruit in plastic containers reads on placing the fruit in trash bags or a plastic bin to transport them to the site where the fruit will be processed into juice. Again, the fruit does not have to be stored for any specified length of time and therefore, 'placing the ripened fruit in plastic lined containers' is directed toward leaving the fruit in the containers for a very minute amount of time or any amount of time. Hence, the use of a container to transport fruits and vegetables was well-known in the art and the choice of container; i.e., plastic -vs- cloth, would have been functional equivalent choices. This is especially true in view of Beaven who specifically teaches storing/ripening fruit in a plastic container.

While Elliot does not specifically teach the psig or the psi of the centrifuge in operation, the psig or psi would be determined based upon the centrifugal force which is based upon the revolutions per second and also based upon the size of the vessel. It is deemed that the operating pressure of the centrifuge would vary between centrifuges and is not related to the crux of Applicants' invention and is also not deemed to be correlated to an unexpected result. The ordinary artisan would have been motivated to use a centrifuge to successfully separate the solid matter of the juice from the liquid matter and it is further deemed that the psig would be routinely modified to optimize filtration using centrifugation. Further, in view of Astrauskas et al. (US 3,953,582) centrifuges operating within the psig as Instantly claimed were known in the art at the time the invention was made. The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000).

Further, [If]... there are [a] finite number of identified, predictable solutions, [a] person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary

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skill and common sense, not innovation *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007.

While Applicant indicates that the method of the claimed invention provides for advantageous results with regard to preserving the natural ingredients of noni juice, it remains deemed that the process steps are made obvious by the combination of the prior art references. The steps in the method were known in the art prior to Applicant's invention. These process steps for preparing juice were well known and documented in the art. There is nowhere in the Instant specification as filed which indicates that the MC juice manufactured by the steps claims *fairs any better than any known MC juice* with regard to biochemical processes such as oxygen scavenging. Applicant has not positively verified that manufacture of MC juice as set forth in the Instant claims preserves crucial active ingredients over MC juice which was known in the art. Therefore, lacking any evidence of unexpected results, it is deemed that the combination of the references makes obvious the claimed invention.

Applicant argues that "The Federal Circuit recently reaffirmed that in order for a reference to anticipate the claims...must provide a certain amount of disclosure..'the disclosure in a assertively anticipating reference must be adequate to enable possession of the desired subject matter' Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research..." . However, it appears that Applicant is not considering the claimed rejection as a whole under the statute of 35

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USC 103(a). The cases cited by Applicants are particularly directed toward rejections under 35 USC 102(b) and not 35 USC 103(a). Nevertheless, it is deemed that the prior art as a whole did put the public in possession of the claimed embodiments in that all of the claimed embodiments were taught or suggested by the prior art cited of record in the outstanding rejections. Applicant has not specifically indicated any embodiment which is found in the claims which was not found in the prior art and merely alleges that the claimed invention is non-obvious over the combination of the prior art references.

Applicant again states that the references are not enabling: "Chye and Schechter both indicate that Tahitian Noni juice was ingested, but neither prior art reference disclosed the method for production...the references do not place one skilled in the art in possession of the products which are discussed, and do not place one of skilled in the art in possession of all of the claim limitations of the present invention " (p. 9, Remarks). This argument is essentially rendered moot in light of the incorporation of Elliot into the rejection. However, it is noted that the references are enabled in that they disclosed Tahitian noni juice, which contained MCJ, blueberry and grape juice which was well known to be consumed. Lipid scavenging must have been an intrinsic consequence of the ingestion of this juice, and it must have scavenged lipids at the same intensity as that of the TNJ of the Instant specification in that they are deemed the same product. The particular manufacturing methods are deemed to be obvious in light of the combination of the references. Again, it is deemed that the manufacturing methods as claimed would have produced MCJ which would have been the same, or so

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similar to MCJ of the prior art that no discernable differences could be established.

Applicant has not provided any evidence that the juice manufactured by the process as recited in the claims has any unexpected results over MCJ or TNJ of the prior art.

According to Applicant's remarks (i.e., p. 10) , it appears that Applicant is stating that the Inventors performed the claimed invention with all of the method steps to prepare Tahitian Noni Juice ® as disclosed by Chye, but that the method for preparing TNJ was not known prior to this application; in Applicant's words, it was a 'secret method'. Applicant indicates that this process (as claimed, and according to Chye) preserved the active ingredients of TNJ. First, it is noted again, that Chye is not relied upon in a vacuum, this reference is combined with others in order to present the rejection under 35 USC 103(a). Chye did not teach the method for manufacture as Instantly claimed, hence the reasoning for combining Chye with the other references cited in the rejection. However, what Chye did teach, and what the reference is enabled for is that TNJ, comprising MC juice, grape juice and blueberry juice was known in the art and consumed at the time the Instant Invention was made.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

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ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patricia Leith
Primary Examiner
Art Unit 1655

January 2, 2008

/Patricia Leith/

Primary Examiner, Art Unit 1655